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O'Shea Getz P.C. 1500 MAIN ST. SUITE 912 SPRINGFIELD, MA 01115			EXAMINER HAMMOND, CHARLES	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,695	Applicant(s) WARDLAW, STEPHEN C.	
	Examiner CHARLES HAMMOND	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 13-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. In response to applicant's amendment to the specification to fix a typographical error the examiner removes the previous objection to the specification.
2. In response to applicant's amendments to claims 1 and 33, the previous rejections remain as previously applied with slight modifications as presented below.
3. In response to applicant's addition of claims 34-36 a new rejection is presented below.

Claim Rejections - 35 USC § 112

4. Claims 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 34 states that "the separators are independent of the first planar member and second planar member". However, the separators in the instant application are a part of the first or second planar member in that they are sprayed on in a solution of phyatgel (see page 8 [0025 of the specification). This implies that the beads become an integral part of the planar member onto which they are sprayed because they become attached to the planar member. For the purposes of examination, it assumed that applicant means to that the separators are not a formed as part (meaning that the separators are not molded as part of the planar members) of the first or second member when it is stated that the separators are "independent".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3, 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Austin et al. (U.S. Patent No. 6,632,652), hereinafter referred to as “Austin”

In regards to claim 1, Austin teaches an apparatus (80) comprising a first planar member (26), a second planar member (88), wherein at least on the first planar member and second planar member is transparent; and

at least three separators (62) disposed between the planar members, each separator individually having a height and the separators collectively having a mean height,

and wherein at least one of the first planar member, second planar member, or separators is sufficiently deformable (***Austin teaches that the cover is made of an elastomeric material. Elastomeric materials are polymeric materials with large amounts of reversible deformability***) (see column 9 lines 29-67, column 10 lines 1-22, column 10 lines 59-52, and Fig. 7) ***when the first planar member and second planar member are drawn toward one another by capillary force from a biological***

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fluid quiescently residing within the chamber to cause the chamber height to be substantially equal to the mean height of the separators. (Austin discloses that the height and width of the separators (bunkers 62) is between 1-50 μ m and 0.01-20 μ m depending on the biological material to be separated) (see column 4 line 54 through column 5 line 10). This range encompasses the disclosed range of 4 μ m in the instant application. Therefore, the apparatus of Austin is capable of creating capillary force when a biological fluid is present between the first planar member and the second planar member.

In regards to claim 2, Austin teaches an apparatus wherein at least one of the first planar member and second planar member comprises flexible plastic (see column 10 lines 1-15)

In regards to claim 3, Austin teaches an apparatus wherein both of the planar members comprise flexible plastic (see column 10 lines 1-15 and column 7 lines 44-49).

In regards to claim 7, Austin teaches an apparatus (80) wherein the separators (62) are attached to at least one of the first planar member (26) or second planar member (88) (see column 9 lines 66-67, column 10 lines 1-5 and Fig. 7).

In regards to claim 11, Austin teaches that the separators are projections of uniform height (see column 9 lines 46-53 and column 4 lines 18-40 and Figs. 2-4).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
10. Claims 4-6 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Austin.

11. In regards to claim 4, Austin teaches the apparatus as described above.

Austin does not specifically teach an apparatus wherein the separators are deformable relative to the first planar member and the second planar member.

12. However, Austin does teach a second planar member (88) made of materials such as silicon, quartz, sapphire, or even an elastomer. Austin also teaches that the first planar member (26) is formed using an elastomer (see column 7 lines 44-53). The separators, which are made of an elastomer, would be more deformable than a very rigid material such as silicon. Furthermore, the separators being very small projections made of the same material as the first planar member (26) would have greater deformability than the large base. So, the separators would be deformable relative to the planar members.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include separators that are deformable relative to the first and

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second planar members for the benefit of creating a seal between the planar members and the separators.

In regards to claims 5 and 6, Austin teaches the apparatus as described above. Austin does not specifically teach an apparatus wherein the separators are deformable relative to the first planar member and the second planar member, or that the first planar member has greater deformability relative to the second planar member and the separators.

However, Austin does teach a second planar member (88) made of materials such as silicon, quartz, sapphire, or even an elastomer. Austin also teaches that the first planar member (26) is formed using an elastomer (see column 7 lines 44-53). The separators, being made of elastomer, would have greater deformability than the second planar member which is made of a rigid material such as silicon or quartz. Furthermore, the separators being very small projections made of the same material as the first planar member (26) would have greater deformability than a base (26). Also, the base could be made sufficiently thin so that it is more deformable relative to the separators. So, one of the separators, first planar member, and second planar member, would have greater deformability relative to at least one of the others for the benefit of creating a seal between the planar members and the separators. Furthermore, the first planar member could have greater deformability than the second planar member and the separators.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a first planar member, a second planar member, or

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separators that have greater deformability relative to one of the others, or to include a first planar member that has greater deformability than the second planar member and the separators for the benefit of creating a seal between the planar members and the separators.

In regards to claim 33, Austin teaches an apparatus (80) comprising a first planar member (26), a second planar member (88), wherein at least on the first planar member and second planar member is transparent and

at least three separators (62) disposed between the planar members, each separator individually having a height and the separators collectively having a mean height (see column 9 lines 29-67, column 10 lines 1-22, and Fig. 7);

Austin does not specifically teach an apparatus wherein at least one of the first planar member, second planar member, or separators is sufficiently deformable and wherein at least one of the first planar member, second planar member, or separators is sufficiently deformable **(Austin teaches that the cover is made of an elastomeric material. Elastomeric materials are polymeric materials with large amounts of reversible deformability) when the first planar member and second planar member are drawn toward one another by capillary force from a biological fluid quiescently residing within the chamber to cause the chamber height to be substantially equal to the mean height of the separators. (Austin discloses that the height and width of the separators (bunkers 62) is between 1-50 μ m and 0.01-20 μ m depending on the biological material to be separated) (see column 4 line 54 through column 5 line 10). This range encompasses the disclosed range of 4 μ m**

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in the instant application. Therefore, the apparatus of Austin is capable of creating capillary force when a biological fluid is present between the first planar member and the second planar member.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a first planar member, second planar member or separators that are sufficiently deformable ***when the first planar member and second planar member are drawn toward one other by capillary forces from a biological fluid quiescently residing with the chamber to cause*** the chamber height to be substantially unaffected by the presence of debris for the benefit of creating a seal between the planar members and the separators.

13. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Austin as applied above in view of Bisconte (U.S. Patent No. 4,883,642), hereinafter referred to as "Bisconte".

Austin teaches the apparatus as described above, however Austin does not teach an apparatus wherein at least one of the first planar member or second planar member comprises linked rigid elements.

In the analogous art of holding, treating, storing and analyzing fixed or living biological samples automatically or continuously Bisconte teaches an apparatus with a first planar member (ribbon 1a) and second planar member (film 21) wherein one of the first planar or the second planar member comprises linked rigid elements (longitudinally extending biological storage zones) and the other of the first planar member or second planar member comprises flexible plastic (see column 9 lines 29-35, column 10 lines

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61-68, and Figs 5a and 5b). This is for the benefit of separating different wells for the continuous processing of biological samples.

Therefore it would have been obvious to one of ordinary skill at the time of the invention to include the linked rigid elements in the Austin apparatus in view of Bisconte for the benefit of creating separate biological chambers.

14. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Austin as applied above in view of Vermeiden et al. (U.S. Patent No. 6,551,554), hereinafter referred to a "Vermeiden".

Austin teaches the apparatus as described above and teaches the use of a dye to allow for the visualization of blood cells (see column 13 lines 35-42), however Austin does not teach separators that a slightly compressible plastic beads, **or separators coated with dye.**

In the analogous art of counting microscopic particles in a liquid medium, Vermeiden teaches the use of plastic beads **coated with a material (polyester material)** for the benefit of creating the depth of the counting compartment (see column 1 lines 45-50, **and column 3 lines 29-35**).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Austin apparatus in view of Vermeiden to include plastic beads **coated with material, including dying material**, as the separation medium for the benefit of creating separation between the two plates.

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15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Austin as applied above in view of Böhm (U.S. Patent No. 7,179,423), hereinafter referred to as "Böhm".

Austin teaches the apparatus as described above, however, Austin does not teach an apparatus wherein one of the first planar member or second planar member comprises one or more ports.

In the analogous art of microscale fluid handling, Böhm teaches an apparatus with a first and second member with one of the members comprising a port (17) (see column 12 lines 4-23 and Fig. 2b) for the benefit of allowing fluid enter the testing region and for the benefit of performing large numbers of chemical operations in a highly parallel fashion (see column 1 lines 36-40) and for the benefit of significantly reducing the amount of liquid sample needed (see column 10 lines 43-46).

Therefore, it would have been obvious to one of ordinary skill at the time of the invention to modify the Austin invention in view of Böhm to include ports for the benefit of allowing fluid to enter the testing and area and for the benefit of performing large numbers of chemical operations quickly and reducing the amount of liquid volume needed for them.

16. **Claims 34-36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Austin as applied above in view of Smith (U.S. Patent No. 4,950,455), hereinafter referred to a "Smith".

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17. In regards to claim 34, Austin teaches the apparatus as described in claim 1 above.

Austin does not teach separators that are independent of the first planar member and second planar member, and are randomly distributed.

In the analogous art of counting microscopic particles, Smith teaches the use of separators (beads 16) that are independent (not formed as part of the substrate (slide 10) and randomly distributed within a chamber (counting chamber 24). Smith teaches dropping beads onto the surface and does not disclose ordering the beads in any way, and Fig.7 shows beads distributed in different random orientations for the benefit of creating a known chamber height (see column 9 line 62 through column 10 line 8, column 10 line 33-42, column 12 lines 31-49, and Figs. 1 and 7).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include separators that are independent from the planar members and separators that are randomly distributed in the Austin apparatus in view of Smith for the benefit of creating a known chamber height.

18. In regards to claim 35, the previous combination remains as applied above. Furthermore, Austin teaches that the distance between the bunkers (S_d) would be varied depending on the material to be separated. A change in the separation distance (number of separators disposed in a given area) would not effect the chamber height if separators of the same type (same height) were disposed in the area (see column 4 line 54 through column 5 line 10).

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19. In regards to claim 36, the previous combination remains as applied above.

Furthermore, Austin teaches that the bunkers have a concentration (they have a specified separation distance (S_d)) and increasing the concentration would not appreciably change the chamber height (making an array of separators with height (h) with a smaller separation distance would not change the chamber height) (see column 4 line 54 through column 5 line 10).

Response to Arguments

20. Applicant's arguments filed February 5th 2010 have been fully considered but they are not persuasive.

21. Applicant argues that Austin does not teach a planar member that is sufficiently deformable under capillary force to cause the chamber height to be substantially equal to the mean height of the separators. The examiner respectfully disagrees with this argument. Austin teaches an apparatus that utilizes a silicone elastomer (instant application also teaches the use of silicone (see page 7 [0021] of the specification), it is noted that the silicone is taught for the beads, but applicant also discloses that beads will be sufficiently deformable under capillary action). Austin also teaches supporting the "delicate" cover (see column 10 lines 49-52). This would suggest that the cover is quite deformable and would deform under capillary forces. Therefore, the cover would inherently have the flexibility to deform under a capillary force.

22. Applicant argues that there is no disclosure whatsoever in Austin that: 1) the cover deforms other than to be peeled back; 2) the cover is sufficiently deformable

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under capillary force from a biological fluid quiescently residing with the chamber; or 3) the cover deforms in a manner that will cause the chamber height to be substantially equal to the mean height of the separators throughout the chamber. However, the examiner points out that the size of the separators in the Austin apparatus encompasses the disclosed size in the instant application (see above); therefore, capillary action would be expected. In addition to this, the elastomeric cover would deform to cause the chamber height to be substantially equal to the mean height of the separators. Austin teaches that the elastomeric cover that engages the top of the bunkers (see column 10 lines 1-7 and Fig. 7). Therefore, the cover causes the chamber height to be substantially equal to the mean height of the separators because it contacts the separators, making the height of the chamber equal to the height of the separators. Furthermore, the fact that Austin teaches a cover that is deformable for the benefit of being able to be peeled back is a functional teaching in Austin. Austin still teaches all of the structural limitations recited in amended claim 1 of the instant application. Furthermore, the fact that Austin teaches a cover that can be peeled back shows that the material of the cover is quite deformable. Austin also describes a support 106 for supporting the "delicate" elastomeric cover. This also implies that the cover is quite deformable (see column 10 lines 49-52).

23. Applicant argues that Austin teaches away from a device having a chamber substantially equal to the mean height of the separators. The examiner respectfully disagrees. Austin teaches an elastomeric sheet that contacts the bunkers of the device. Therefore, the sheet would lie over the bunkers can create a chamber height that is

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substantially equal to the mean of the bunker heights. The elastomeric sheet is made of a deformable material and would be capable of deforming to accommodate differing bunker sizes.

24. Applicant argues that Austin does not teach a separator that is deformable under capillary force to cause the chamber height to be substantially deformable relative to the mean height on the separators. As previously stated Austin does not specifically teach separators that are sufficiently deformable. However, Austin does teach that the separators (part of the substrate) are made from an elastomeric material, and that the cover can be made from an elastomeric material for the benefit of creating a reversible seal (note that Austin states the entire device can be made from elastomeric materials, Austin does not require that one piece (cover or substrate) be made from a rigid material such as silicon). Furthermore, the separators being small projections would make them quite deformable because of their small dimensions (see column 7 lines 31-53, and column 4 line 54 through column 5 line 10). Applicant also argues that including deformable separators would render the Austin apparatus inoperable. However, deformability of the separators in Austin would not render the device inoperable, it may slow the separation of particles or cause more particles to be separated, but the device would still accomplish the separation. While Austin does not specifically teach separators that are sufficiently deformable under capillary force it does not mean the device is incapable of performing such a function. Therefore, since Austin teaches the use of elastomeric materials for the separators and teaches a size of the separators consistent with the instant application, it would have been obvious to one of ordinary

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skill in the art at the time of the invention to include sufficiently deformable separators for the benefit of creating a reversible seal (see column 1 lines 45-50, and column 3 lines 29-35).

25. Applicant further argues that Austin teaches the use of sealing means for attaching the cover and therefore would mean that Ausin teaches away from the use of a cover that attaches using capillary force. However, it is noted that Austin teaches the use of "bonding" and "electrostatic" sealing for use with the rigid cover (see column 5 lines 11-37 and column 6 lines 31-39). Applicant is discussing prior art in these sections. Applicant does teach "spontaneous sealing" with respect to the flexible cover. While Austin states "spontaneous sealing", the dimensions of the Austin apparatus are consistent with the dimensions of the instant application and therefore capillary action between the cover and the substrate is to be expected when a fluid is present.

26. The rejections of claims 8 and 9 remain as previous applied in view of modified rejection of claim 1 presented above.

27. Applicant argues that the rejection of claim 10 is inappropriate because Vermeiden does not teach disclose particles uniformly coated with dye, and Vermeiden does not teach compressible beads because aluminum oxide, glass, and many plastics are considered incompressible. Ausin teaches the use of a dye but does not teach coating the flexible separators with it (see column 13 lines 35-42). Austin also teaches the use of flexible separator, but does not teach flexible separators that are beads. Vermeiden teaches the use of plastic beads in the art, and also teaches the use of coating the plastic beads with material (adhesive). While Vermeiden does not expressly

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state beads that are deformable under capillary forces, the use of plastic beads is still present. In addition, while Vermeiden does not specifically teaches coating the beads with dye, the treating (or coating) of beads is present. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use plastics beads as the separators, and coat the plastic beads with dye in the Austin apparatus in view of Vermeiden.

28. The rejection of claim 12 remains as previous applied in view of modified rejection of claim 1 presented above.

Conclusion

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHARLES HAMMOND whose telephone number is (571)270-3595. The examiner can normally be reached on 8am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHARLES HAMMOND/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797